King, Valerie A.

From: Kimberly Prchal [Kimberly.Prchal@mdsps.com]
Sent: Friday, September 12, 2003 8:57 PM
To: Barbara.K.Zedler; Michael.Szwanek
Cc: Maria.Gogova; Valerie.A.King; Paul.Mendes
Subject: Re: WatchPC script IRB approval

Sensitivity: Confidential

Barbara,

I say wait and send the script and the instruction booklet to the IRB at the same time. They can review the entire packet, then later the Spanish certification for the booklet.

I HIGHLY doubt IRB will change any of the script.

Kim

Kim and MIke,

WatchPC wants to get a few prototypes made next week. The script (final revised per PM and MDS comments, w/ our Legal approval, hopefully available later today) and instruction bklet need to get IRB approval. Should we send the script upon acceptance NOW, or wait and send both (prob end of) next week, allowing WatchPC to program w/ an unapproved script and possibly have to adjust after IRB review? How long to get (expedited, I hope) IRB approval? Thanks.

Barb

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